



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
555 Winderley Place, Suite 200
Maitland, Florida 32751

5/4/98
T1761M

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-98-36

March 9, 1998

Danny Sheetz, President
Sun Medical Supply, Inc.
1825 S. Division Avenue
Orlando, Florida 32805

Dear Mr. Sheetz:

We are writing to you because on February 23-25, 1998, FDA Investigator R. Kevin Vogel collected information that revealed serious regulatory problems involving oxygen analyzers (for use with oxygen concentrators only) which are manufactured and distributed by your firm (Class II).

Under the Federal Food, Drug, and Cosmetic Act (The Act), these products are considered to be medical devices because they are used to test medical devices which are subsequently used to treat a medical condition or to affect the structure or function of the body. The law requires that manufacturers of medical devices conform with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation as specified in Title 21, Code of Federal Regulations (CFR), Part 820. The 1978 Good Manufacturing Practice (GMP) for Medical Devices regulation was superseded on June 1, 1997, by the Quality Systems regulation which incorporates the device GMP.

The inspection revealed that the devices are adulterated within the meaning of section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacture, processing, packing, storage, or distribution are not in conformance with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation. These violations include, but are not limited to the following:

- Failure to establish and maintain a written corrective and preventive action program, e.g., there is no written procedure that includes instructions to analyze and investigate all possible sources of data to identify potential and real causes of nonconforming product, to identify action(s) needed to make corrections, and to verify or validate that corrective actions are effective (FDA 483, Item #1).
- Failure to establish and maintain procedures for receiving, reviewing and evaluating complaints, e.g., complaint investigations are not adequately documented, consumer complaint trends are not determined, and service reports are not distinguished from complaints (FDA 483, Item #2).
- Failure to assure that quality assurance requirements are effectively established and maintained, e.g., Quality assurance checks or wrist straps for Electronic Discharge are not documented, in-process rejects found during QA checks are not documented, personnel qualifications for employees who perform hand soldering operations are not documented, and quality inspections of soldering completed during processing of p.c. boards are not documented (FDA 483, Item nos. 5, 6, & 7 & 11).
- Failure to develop, conduct, and monitor production processes assuring that devices conform to established specifications, e.g., specifications require device accuracy to be $\pm 2\%$ full scale and repeatability to be $\pm 0.5\%$, however this is not verified (FDA 483, Item #3).
- Failure to establish procedures for quality audits and the conduct of audits to assure that the quality system is in compliance with established requirements and to determine the effectiveness of the QA system, e.g., there is no documented audit schedule or criteria and no audits have been conducted (FDA 483, Item #8).
- Failure to establish and maintain procedures for changes to specifications, processes, or procedures assuring that all changes are verified or where appropriate validated before implementation and are documented accordingly (FDA 483, Item #9).
- Failure to document the calibration of equipment used to measure the accuracy and precision limits assuring the quality of a device (FDA 483, Item #10).
- Failure to establish and maintain procedures assuring that incoming components meet specifications, e.g., vendor supplied fuel cells are not checked or documented as meeting specifications (FDA 483, Item #12).

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- Failure to establish and maintain written MDR procedures (FDA 483, Item #13).

You should know that these are serious violations of the law that may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of the product, or assessing civil money penalties. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the Inspectional Observations (FDA 483) issued to you at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. Also, other Federal agencies are informed about the warning letters we issue, such as this one, so that they may consider this information when awarding government contracts.

It is necessary for you to take action on this matter. Please let this office know in writing within 15 working days of receipt of this letter what steps you are taking to prevent this from happening again. If you need more time, let us know why and when you expect to complete your correction. Please direct your response to Timothy J. Couzins, Compliance Officer, Food and Drug Administration, Florida District, 555 Winderley Place, Suite #200, Maitland, Florida 32751.

If you have more specific questions about the Quality System Regulation and how they affect your particular device, or about the content of this letter, please contact Tim Couzins at (407) 475-4728.

Sincerely,

A handwritten signature in dark ink, appearing to read "Douglas D. Tolen", with a stylized flourish at the end.

Douglas D. Tolen
Director, Florida District